REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Amendments to Specification and Abstract

The specification and abstract have been amended to replace "sugar ester fatty acid" with "sucrose ester fatty acid", which is the appropriate term based on the original Japanese PCT application, upon which this application is based. Support for this amendment is also found in the Japanese priority application. A Substitute Specification and Abstract are submitted herewith.

No new matter has been added to the application by this typographical correction.

Claim Amendments

Claims 4, 8, 24 and 25 have been amended to better conform with U.S. practice.

Claims 27-30 have been cancelled, without prejudice.

New claims 31-38 have been added to the application. Support for these claims is found on page 6, lines 31-36 and Tables 1 and 2 of Applicants' original specification.

Claims 1, 2 and 20-22 have also been amended to replace "sugar ester fatty acid" with "sucrose ester fatty acid", which is the appropriate term based on the original Japanese PCT application, and the Japanese priority application for this application.

Thus, no new matter has been added to the application.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 2, 5 and 9-11 as being indefinite under 35 U.S.C. § 112, second paragraph is respectfully traversed.

The Examiner takes the position that efficacy is a relative term, and states that it is unclear from the specification as to which effect of the drug the 100 mg efficacy pertains.

Applicants respectfully disagree with the Examiner's position. "Efficacy" (potency) is a unit of an effective amount of antibiotics. Specifically, the "efficacy" is a unit commonly used for expressing an amount of an active moiety of an antibiotic. For

example, when a certain antibiotic is provided as a salt, an amount of its salt-free form is expressed for an effective amount of the antibiotic.

Since cefditoren pivoxil is provided as an ester form, an amount of its ester-free form is expressed for an effective amount of cefditoren pivoxil.

For evidence, attached hereto are the relevant pages of the Japanese Pharmacopoeia Fifteenth Edition (English version), which indicates that the potency (efficacy) of cefditoren pivoxil is expressed as mass (potency) of cefditoren.

Further, also attached hereto is the notification by the Ministry of Health, Labour and Welfare in Japan, which indicates that the name and standards for the drugs concerned officially conform to those set forth in the Japanese Pharmacopoeia Fifteenth Edition.

According to MPEP 2173.02, the definiteness of claim language must be analyzed, not in a vacuum, but in light of the specification, the teachings of the prior art and the interpretation which would be given to the claim by one of ordinary skill in the art. As Applicants have shown, "efficacy" is understood by those skilled in the art as a unit used for expressing an amount of an active moiety of an antibiotic.

Therefore, Applicants assert that the term "efficacy" is not a relative term. Accordingly, the above rejection is untenable and should be withdrawn.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Rejection Under 35 U.S.C. § 103(a)

The rejection of claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Shimizu et al. (WO 00/06126) and Onodera et al. (U.S. 6,486,149) and further in view of Sigma-Aldrich catalog entry for Tween 80, is respectfully traversed.

Applicants assert that the obviousness rejection is untenable for the following reasons.

The Examiner has erroneously interpreted the Shimizu et al. reference.

Applicants' independent claims 1 and 20 require a pharmaceutical composition comprising amorphous cefditoren pivoxil and a sucrose ester fatty acid...". The Examiner asserts that Shimizu et al. teach a sugar ester fatty acid (Polysorbate 80, also known as sorbitan monooleate), in Example 1 (on page 33 in the Table corresponding to the Enteric film coating liquid). However, contrary to the Examiner's assertion, Polysorbate 80 (sorbitan monooleate) is **not** a sucrose ester fatty acid. The Examiner is respectfully referred to the definitions of Polysorbate 80 obtained from the web pages of the U.S. Food and Drug administration (copy attached).

Furthermore, claim 1 of Shimizu et al. requires a sugar, not a sugar ester fatty acid. (It is noted that Applicants' claims have been amended to recite *sucrose* ester fatty acid.)

The Examiner has relied upon Shimizu et al. as teaching Applicants' required component of the sucrose ester fatty acid. However, as discussed above, this component is not present in the Shimizu et al. reference. Further, this deficiency is not remedied by either of the secondary references. Accordingly, for this reason alone, the rejection is untenable and should be withdrawn. However, Applicants provide the following additional comments, in order to expedite allowance of the present application.

The present application provides working examples showing the advantages of the addition of sucrose ester fatty acid in replace of Polysorbate 80.

As described on page 4, lines 20 to 23 of the original specification, Applicants found that crystallization of amorphous cefditoren pivoxil was inhibited by simply mixing amorphous cefditoren pivoxil with a sugar ester fatty acid.

Specifically, the compositions of Examples 1 to 5 in Table 1 include amorphous cefditoren pivoxil and sucrose ester fatty acid while the composition of Reference Example 2 in Table 1 is a comparative composition containing polysorbate 80 in place of sugar ester fatty acid. These compositions were tested in accordance with the procedure of Test Example 1.

As shown in Table 2, Reference Example 2 containing polysorbate 80 was immediately converted to a crystalline form while Examples 1 to 5 containing sucrose fatty acid with amorphous cefditoren pivoxil exhibited the amorphousness-retaining

character of amorphous cefditoren pivoxil for at least two days. These results indicate that the claimed pharmaceutical compositions containing amorphous cefditoren pivoxil achieve high oral absorbability.

Furthermore, none of the cited references teach or suggest the problem to be solved by the present application. Specifically, as stated on page 4, lines 9 to 33 of Applicants' specification, the problem to be solved in the present application is to prevent amorphous cefditoren pivoxil from changing into a crystalline state in a solution, thereby improving the oral absorbability. However, none of the cited references even mention that amorphous cefditoren pivoxil is apt to change into a crystalline state in a solution, or that such a change adversely affects the oral absorbability. Accordingly, the cited references fail to recognize the problem discussed in Applicants' invention, and therefore do not teach or suggest a solution to said problem.

Additionally, Shimizu et al. fail to teach or suggest "amorphous" cefditoren pivoxil. Although Onodera et al. disclose amorphous cefditoren pivoxil, the reference fails to teach or suggest the problem to be solved in the present application. Additionally, Onodera et al. fail to remedy the deficiency of Shimizu et al. by teaching a sugar ester fatty acid.

For the reasons set forth above, the subject matter of Applicants' claims is clearly patentable over the cited combination of references. Accordingly, the rejection should be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

Yukiko YOKOI et al.

By: _____

Amy E. Schmid
Registration No. 55,965
Attorney for Applicants

AES/emj
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
August 1, 2008

Attachments: Pages of Japanese Pharmacopoeia Fifteenth Edition
Notification by the Ministry of Health, Labour and Welfare in Japan
Definition of Polysorbate 80 from webpages of FDA
Substitute Specification (marked up copy)
Substitute Specification (clean copy)